IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

SEPRACOR, INC.,)
Plaintiff,)
v.) C.A. No. 06-113-JJF) (Consolidated)
DEY, L.P. and DEY, INC.,	
Defendants.)) DEDACTED
SEPRACOR, INC.,) <u>REDACTED</u>) <u>PUBLIC VERSION</u>
Plaintiff,)
v.	.)
BARR LABORATORIES, INC.,)
Defendant.)

DECLARATION OF SAM V. DESAI IN SUPPORT OF DEFENDANTS DEY, L.P. AND DEY, INC.'S RESPONSIVE CLAIM CONSTRUCTION BRIEF

(VOLUME IV – EXS. 25-27)

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Dated: May 1, 2008

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Plaintiff,)
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Defendants.)
) C.A. No. 06-113 (JJF)
SEPRACOR, INC.,) (Consolidated)
Plaintiff,	j
v.)
BARR LABORATORIES, INC.,)
Defendant.)
	j

DECLARATION OF SAM V. DESAI IN SUPPORT OF DEFENDANTS DEY, L.P. AND DEY, INC.'S RESPONSIVE CLAIM CONSTRUCTION BRIEF

- I, Sam V. Desai, am a member of the law firm Frommer Lawrence & Haug LLP, counsel for Defendants, Dey, L.P. and Dey, Inc. I make this declaration in support of DEFENDANT'S DEY, L.P. AND DEY, INC.'S RESPONSIVE CLAIM CONSTRUCTION BRIEF.
 - Attached as Exhibit 25 is a chart summarizing the parties' proposed constructions. 1.
- Attached as Exhibit 26 is a true and accurate copy of the Supplemental Report of 2. Richard C. Ahrens, M.D., dated January 17, 2008 (filed under seal).
- Attached as Exhibit 27 is a true and accurate copy of a March 26, 1999 letter from 3. Joan Hankin, J.D., Regulator Review Officer, Division of Drug Marketing, Advertising, and

I declare under penalty of perjury that the foregoing is true and correct.

Dated: May 1, 2008

Sam V. Desai

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EXHIBIT 25

US PATENT NO. 5,362,755

†	NOTITIALISMOO	CONSTRUCTION	CONSTDICTION
"while reducing side effects 1	The side effects are those associated	Reducing those beta-adrenergic side	"Side effects" are "[c]entral nervous
	with chronic administration of racemic	effects and teratogenic effects	system effects (such as tremor,
tion of racemic	albuterol. The side effects are not	associated with the periodic or	nervousness, shakiness, dizziness and
	limited in scope to the examples that are	prophylactic administration of albuterol	increased appetite), cardiac effects (such
(claim 1)	specifically identified in the patent	that are caused directly by the S(+)	as cardiac arrhythmia), and teratogenic
82.	specification.	enantiomer of albuterol.	effects associated with chronic
			administration of racemic albuterol."
			See '755 Patent, col. 3 Il. 28-31, 33-35.
	The side effects are those associated	At the same time the optically pure R(-)	"Side effects" are "[c]entral nervous
reducing undesirable side	with chronic administration of racemic	isomer is administered in a quantity	system effects (such as tremor,
effects"	albuterol. The side effects are not	sufficient to cause bronchodilation there	nervousness, shakiness, dizziness and
(claim 1)	limited in scope to the examples that are	is a reduction in those beta-adrenergic	increased appetite), cardiac effects (such
3	specifically identified in the patent	side effects and teratogenic effects	as cardiac arrhythmia), and teratogenic
83.	specification.	associated with the use of racemic	effects associated with chronic
		albuterol that are caused directly by the	administration of racemic albuterol."
		S(+) enantiomer of albuterol.	See '755 Patent, col. 3 11. 28-31, 33-35.
ally administering"	"Chronic administration" and	Treating periodically or	"Chronic" should mean "prophylactic or
(claim 1)	"chronically administering to the	prophylactically.	periodic."
•#	individual" mean to administer the drug		
4	to a human on a recurring basis to		
<u> </u>	prevent or reduce the extent to which		
.	bronchospasms occur.		

US PATENT NO. 5,547,994

DISPUTED TERM	SEPRACOR'S PROPOSED	DEY'S PROPOSED	BARR'S PROPOSED
(CLAIM #)	CONSTRUCTION	CONSTRUCTION	CONSTRUCTION
"while reducing side effects	The side effects are those associated	Reducing those beta-adrenergic side	"Side effects" are "[c]entral nervous
associated with the acute	with acute administration of racemic	effects and teratogenic effects	system effects (such as tremor,
administration of racemic	albuterol. The side effects are not	associated with the administration of	nervousness, shakiness, dizziness and
albuterol"	limited in scope to the examples that are	racemic albuterol to a patient after the	increased appetite), cardiac effects (such
(claim 1)	specifically identified in the patent	onset of an asthma attack that are caused	as cardiac arrhythmia), and teratogenic
	specification.	directly by the S(+) enantiomer of	effects associated with chronic
		albuterol.	administration of racemic albuterol."
			See '755 Patent, col. 3 Il. 28-31, 33-35.
"while simultaneously	The side effects are those associated	At the same time the optically pure R(-)	"Side effects" are "[c]entral nervous
reducing undesirable side	with acute administration of racemic	isomer is administered in a quantity	system effects (such as tremor,
effects"	albuterol. The side effects are not	sufficient to cause bronchodilation there	nervousness, shakiness, dizziness and
(claim 1)	limited in scope to the examples that are	is a reduction in those beta-adrenergic	increased appetite), cardiac effects (such
	specifically identified in the patent	and teratogenic effects associated with	as cardiac arrhythmia), and teratogenic
	specification.	the use of racemic albuterol that are	effects associated with chronic
		caused directly by the S(+) enantiomer	administration of racemic albuterol."
		of albuterol.	See '755 Patent, col. 3 Il. 28-31, 33-35.

US PATENT NO. 5,760,090

DISPUTED TERM	SEPRACOR'S PROPOSED	DEY'S PROPOSED	BARR'S PROPOSED
(CLAIM #)	CONSTRUCTION	CONSTRUCTION	CONSTRUCTION
"while reducing side effects	The side effects (or adverse effects) are	Reducing those beta-adrenergic side	"Side effects" are "[c]entral nervous
associated with the	those associated with the administration	effects and teratogenic effects	system effects (such as tremor,
administration of racemic	of racemic albuterol. The side effects	associated with the administration of	nervousness, shakiness, dizziness and
albuterol"	are not limited in scope to the examples	racemic albuterol that are caused	increased appetite), cardiac effects (such
(claim 1)	that are specifically identified in the	directly by the S(+) enantiomer of	as cardiac arrhythmia), and teratogenic
	patent specification.	albuterol.	effects associated with chronic
			administration of racemic albuterol."
			See '755 Patent, col. 3 Il. 28-31, 33-35.
"while simultaneously	The side effects (or adverse effects) are	At the same time the optically pure R(-)	"Side effects" are "[c]entral nervous
reducing undesirable side	those associated with the administration	isomer is administered in a quantity	system effects (such as tremor,
effects"	of racemic albuterol. The side effects	sufficient to cause bronchodilation there	nervousness, shakiness, dizziness and
(claim 1)	are not limited in scope to the examples	is a reduction in those beta-adrenergic	increased appetite), cardiac effects (such
	that are specifically identified in the	and teratogenic effects associated with	as cardiac arrhythmia), and teratogenic
	patent specification.	the use of racemic albuterol that are	effects associated with chronic
		caused directly by the S(+) enantiomer	administration of racemic albuterol."
		of albuterol.	See '755 Patent, col. 3 Il. 28-31, 33-35.

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US PATENT NO. 5,844,002

DISPUTED TERM (CLAIM #)	SEPRACOR'S PROPOSED CONSTRUCTION	DEY'S PROPOSED CONSTRUCTION	BARR'S PROPOSED CONSTRUCTION
"inducing bronchodilation or providing relief of bronchospasm" (claims 1 and 10)	"Bronchospasm" means a contraction of smooth muscle in the walls of the bronchi and bronchioles, causing narrowing of the lumen, which is not limited to bronchospasms associated with asthma.	Treating asthma.	Treating asthma or an asthma attack.
"while reducing the concomitant liability of adverse effects associated with racemic albuterol" (claim 10)	The side effects (or adverse effects) are those associated with the administration of racemic albuterol. The side effects are not limited in scope to the examples that are specifically identified in the patent specification.	Reducing those beta-adrenergic side effects and teratogenic effects associated with the administration of racernic albuterol that are caused directly by the S(+) enantiomer of albuterol.	"Adverse effects" are "[c]entral nervous system effects (such as tremor, nervousness, shakiness, dizziness and increased appetite), cardiac effects (such as cardiac arrhythmia), and teratogenic effects associated with chronic administration of racemic albuterol." See '755 Patent, col. 3 II. 28-31, 33-35.
"while simultaneously reducing said adverse effects" (claim 10)	The side effects (or adverse effects) are those associated with the administration of racemic albuterol. The side effects are not limited in scope to the examples that are specifically identified in the patent specification.	At the same time the optically pure R(-) isomer is administered in a quantity sufficient to cause bronchodilation there is a reduction in those beta-adrenergic side effects and teratogenic effects associated with the use of racemic albuterol that are caused directly by the S(+) enantiomer of albuterol.	"Adverse effects" are "[c]entral nervous system effects (such as tremor, nervousness, shakiness, dizziness and increased appetite), cardiac effects (such as cardiac arrhythmia), and teratogenic effects associated with chronic administration of racemic albuterol." See "755 Patent, col. 3 II. 28-31, 33-35.

US PATENT NO. 6,083,993

DISPUTED TERM (CLAIM #)	SEPRACOR'S PROPOSED CONSTRUCTION	DEY'S PROPOSED CONSTRUCTION	BARR'S PROPOSED CONSTRUCTION
"treating bronchospasm in a patient with reversible obstructive airway disease" (claim 1)	"Bronchospasm" means "contraction of smooth muscle in the walls of the bonchi and bronchioles, causing narrowing of the lumen."	Treating an asthma patient after the onset of an asthma attack (acute treatment).	Treating asthma or an asthma attack.
	"Reversible obstructive airway disease" means "a respiratory disorder such as asthma, chronic bronchitis, and emphysema."		
"preventing bronchospasm in a patient with reversible obstructive airway disease" (claim 10)	"Bronchospasm" means "contraction of smooth muscle in the walls of the bonchi and bronchioles, causing narrowing of the lumen."	Chronically treating a patient for asthma.	Preventing asthma or an asthma attack.
	"Reversible obstructive airway disease" means "a respiratory disorder such as asthma, chronic bronchitis, and emphysema."		

EXHIBIT 26

REDACTED

EXHIBIT 27

REDACTED